

REMARKS/ARGUMENTS

Upon entry of the present amendment, claims 1-4, 7-10, 13-16, 19, 21-27, and 28-30 will be pending in this application and presented for examination. Claims 1, 2, 7, 8, 10, 13, 14 and 19 have been amended. Claims 5-6, 11-12 and 17-18 have been cancelled without prejudice or disclaimer. Claims 28-30 are newly added. No new matter has been introduced with the foregoing amendments. Reconsideration is respectfully requested.

I. FORMALITIES

Independent claims 1, 7 and 13 have been amended to incorporate the features of claims 5-6; 11-12 and 17-18, respectively. These features are that the antigen and the interferon α are administered at the same time using nasal administration.

Claims 28-30 are newly added and recite the features of the amended subject matter of claims 2, 8 and 14. As such, Applicants respectfully request that these amendments and new claims be entered.

II. OBJECTIONS

The Examiner objected to claims 1, 5-6, 8, 10, 13-14, 12, 17 and 19 for allegedly various syntax errors and other clarity issues. With respect to the canceled subject matter in claims 5-6, 12 and 17, Applicants submit that these objections have been rendered moot.

With respect to claims 2, 8 and 14, Applicants have added new claims 28-30. In other instances, Applicants have followed the Examiner's suggestions keeping in mind that other changes to the claims have been made. As such, Applicants respectfully request that the Examiner withdraw the objections to the claims.

III. REJECTION UNDER 35 U.S.C. 103(a)

The Examiner has rejected claims 1-19 under 35 U.S.C. § 103(a) as allegedly being obvious over WO 00/20028 ("*Staats et al.*") in view of Takasu, *Kurume Med J.*, 2001, Vol. 48, p. 171-174 ("*Takasu*"). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Applicants state that there is simply no motivation or suggestion provided in the cited references to modify its teaching in the way the Examiner has contemplated. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Staats et al. teach a method for eliciting an immune response against an antigen in a vertebrate by providing an antigen-adjuvant composition. *Staats et al.* teach the use of a substantially non-toxic adjuvant and exemplifies IL-1 α and IL-1 β . Further at the bottom of page 14, bridging to page 15 at the top, *Staats et al.* teach interleukins including:

IL-1 α , IL-1 β , IL-2, IL-5, IL-6, IL-12, IL-15 and IL-18; transforming growth factor beta (TGF β); granulocyte macrophage colony stimulating factor (GM-CSF); interferon-gamma (IFN α); or other cytokine which has adjuvant activity.

Staats et al. teach a method wherein *interferon-gamma* is used. Apparently, *Staats et al.* has decided to define interferon-gamma as "IFN α " and not the traditional --IFN γ --. However, the current claims recite interferon alpha, wherein "IFN α " means interferon alpha and not interferon gamma. In any event, there is certainly no description of the effect of IFN α in *Staats et al.* As such, the claims are not anticipated by *Staats et al.*

Takasu teaches IFN α as an adjuvant with a peptide from a influenza virus as an antigen. Takasu teaches subcutaneous administration (at the base of the tail of mice) of IFN α with a flu peptide. Takasu teach that such inoculation was effective for the induction of peptide specific cytotoxic T lymphocytes (CTL). Takasu does not teach or suggest nasal administration of the IFN α as an adjuvant with a peptide from influenza virus at the same time.

The present claims have been amended to recite that IFN α with the vaccine antigen be administered nasally at the same time. Nasal administration of the vaccine antigen and an INF α that induces both a vaccine antigen-specific antibody in the blood and a vaccine antigen-specific antibody secreted at the mucosal surface is not taught or even suggested in the cited art. As such, Applicants respectfully request that the Examiner withdraw the rejection.

IV. REJECTION UNDER 35 U.S.C. 103(a)

The Examiner has rejected claims 1-19 under 35 U.S.C. § 103(a) as allegedly over U.S. Patent No. 6,436,391 ("Foster *et al.*") in view of U.S. Patent No. 6,361,769 ("Tovey"). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Foster *et al.* teach an adjuvant for a vaccine comprising IFN- α_8 and/or IFN- α_{14} . Tovey teach a method for stimulating the immune response by administering an interferon via oromucosal contact. This apparently is effective in treating autoimmune, mycobacterial, neurodegenerative, parasitic, and viral diseases.


Neither Foster *et al.* nor Tovey teach or suggest the administration of IFN α with the vaccine antigen nasally at the same time. Nasal administration of a vaccine antigen and an INF α that induces both a vaccine antigen-specific antibody in the blood and a vaccine antigen-specific antibody secreted at the mucosal surface is not taught or suggested in the combination of the cited art. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,


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